NR 149 Questions… and More Answers

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Since the Natural Resources Board authorized public hearings for NR 149, the program has received numerous e-mails and phone calls asking how several sections would apply to everyday laboratory operations. We determined that many laboratories were asking similar questions and, as a result, published answers to five of the most-asked questions in the Spring 2006 LabNotes newsletter. This document expands the answers to the questions from the newsletter article and addresses several additional topics as well.

These answers are geared towards those smaller laboratories that analyze samples in support of a WPDES discharge permit. For implications for more complex procedures, including metals and organics, please contact the author. In addition, when analytical method requirements are more stringent that those identified by code, the laboratory must follow the method requirements, unless the code gives specific allowances. When in doubt, defer to method requirements and contact your auditor.

Specific code citations from the NR 149 draft are included to allow you to refer back to the code language.

The topics addressed in this document include:

- Analyst Training and IDCs
- Analytical or Preparation Batch
- Analytical and Technical Records
- Certification and Registration for DO, pH and Total Residual Chlorine
- Enforcement
- Initial and Continuing Calibration Verification
- Laboratory Support Equipment Calibration
- Length of the Current Draft
- Proficiency Testing (PTs, formerly known as reference samples)
- Purpose and Value of Second Source Materials
- Relationship Between Laboratory Control Samples, Matrix Spikes and Quality Control Samples
- Sample Handling and the 15-Minute Rule
- Sample Identification and Labeling

For many of the topics, the impact to daily practices for the routine WPDES-required tests, BOD, Ammonia by ISE, Nonfilterable Residue (TSS) and Total Phosphorus are explained. In addition, the program's plans for assisting laboratories during the implementation of the new rule, through issuance of guidance documents, sample forms and providing training are briefly discussed.

Pages 9 and 10 are comprised of tables describing the calibration and quality control elements, specific requirements and acceptance criteria for these routine WPDES-required tests.

Analyst Training and IDCs [NR 149.36 (3)]

Analysts working in laboratories are exempt from performing an IDC if, in the year before the rule becomes effective, they have successfully analyzed a combination of 4 samples with detectable concentration of analyte for each test, such as blinds, daily "known standards", matrix spikes, reference samples or sample replicates (for example, a total phosphorus IDC could be comprised of 2 known standards analyzed on different days, a reference sample and a matrix spike). A laboratory would have to identify the analyses attributed to each analyst at the time of an audit, if requested. Once an analyst has performed an IDC for a method, another IDC is not required, unless the analyst stops working in the laboratory for more than a year or the laboratory changes instrument or instrument type.

An IDC is not part of the operator certification program, nor does it require outside training or verification, or purchase of additional proficiency testing samples, blinds or other reference materials.

Do I have to perform an IDC? Not necessarily— the draft allows for an analyst to work under the supervision of someone who has completed an IDC. It is not intended to mean "direct supervision" where both analysts are in the laboratory at the same time.

How does this apply to BOD, Ammonia, Nonfilterable Residue (TSS) and Total Phosphorus?

Test	In year prior to effective date, for each analyst:
BOD	Combination of 4 acceptable blinds, GGAs, sample replicates, or reference samples
Ammonia	Combination of 4 acceptable blinds, known standards, matrix spikes, sample replicates, or reference samples
Nonfilterable Residue (TSS)	Residue cannot be spiked, IDC comprised of understanding procedure, as written
Total Phosphorus	Combination of 4 acceptable blinds, known standards, matrix spikes, sample replicates, or reference samples

If your laboratory has analysts that only read back BODs (they do not set up samples), there is no requirement for them to complete the entire process— reading back 4 acceptable blinds, GGAs, sample replicates, or reference samples is sufficient.

Analytical or Preparation Batch? [NR 149.03 (7) and (56)

An analytical batch is a set of any number of samples not requiring preparation, or sample concentrates, digestates, distillates or extracts, analyzed together in an uninterrupted sequence; an analytical batch may consist of samples of various quality control matrices. An analytical batch can be comprised of multiple preparation batches and is not restricted to duration.

A preparation batch is a group of up to 20 samples, excluding quality control samples, of the same quality system matrix processed in a 24-hour period. In the case where a laboratory does not analyze more than 7 samples of any quality control matrix (wastewater effluent and influent are separate QC matrices) for a given test in a week, the preparation batch is defined as one week's worth of samples. This additional definition allows smaller laboratories to analyze a single Laboratory Control Sample (LCS) of GGA for BOD each week, even if required to analyze BODs daily, as is current practice.

How does this apply to BOD, Ammonia, Nonfilterable Residue (TSS) and Total Phosphorus?

Test	Batch Type and Why
BOD	Preparation; samples require incubation
Ammonia	Analytical; samples analyzed directly
Nonfilterable Residue (TSS)	Analytical; samples analyzed directly
Total Phosphorus	Preparation; samples require digestion

Analytical and Technical Records [NR 149.39 (3)]

Of the 21 elements identified in this section, laboratories are currently required to maintain records of all but 2— #10, traceability of standards and reagents used to perform analysis and #20, environmental conditions crucial to tests. Many benchsheets in use capture much of this information already and the program will distribute blank forms and templates for routine WWTP tests and general laboratory operations to further assist laboratories to document compliance. These elements do not have to be consolidated into a single source- just be retained. Tracking of environmental conditions crucial to tests includes such items as temperature of TCLP extractions, which must be performed at a specific temperature range. If your laboratory performs TCLP testing, you are familiar with this requirement and

your records already capture this critical data. This type of information is not required for the routine WPDES tests.

Many small laboratories have been maintaining reagent logbooks for years- they are particularly valuable when trying to attribute quality control failure to a specific lot of reagent (contaminated or "bad" reagents happen, unfortunately). It is the intent of the program to provide forms and templates to all laboratories for tracking reagent and standards with the training materials that will be developed for implementation.

How does this apply to BOD, Ammonia, Nonfilterable Residue (TSS) and Total Phosphorus?

Test	What might be included in a reagent log:
BOD	GGA, nutrients for dilution water preparation, synthetic seed, HCl, NaOH
Ammonia	Standard salts and solutions, second source standard solution, ISE buffer solutions
Nonfilterable Residue (TSS)	None
Total Phosphorus	Standard salts and solutions, second source standard solution, H_2SO_4, ammonium persulfate, phenolphthalein, ammonium molybdate, potassium antimonyl tartrate, ascorbic acid, Test-N-Tube reagents

Certification and Registration for Dissolved Oxygen, Total Residual Chlorine, pH, and Specific Conductance [Appendix I]

Appendix I, Analytical Techniques, Analytes and Analyte Groups for Certification and Registration in the Aqueous and Solid Matrices includes entries in Table 4, Electrometric Assays, for Dissolved Oxygen, pH, Specific Conductance and Chlorine, Total Residual. NR 219.06 excludes these and some other tests from laboratory certification and registration requirements. During the rulemaking process, commercial laboratories requested that the program offer voluntary certification for these tests. Laboratories are not under any obligation to request or maintain certification or registration for these tests.

Enforcement [NR149.10]

DNR follows a stepped enforcement process which typically starts with issuance of a Notice of Noncompliance (NON), or, if warranted, a Notice of Violation. Neither the current code (NR149.42) or the draft detail criteria for the preliminary steps of enforcement, the program would not ever be able to suspend, revoke or refer a laboratory to the Department of Justice for prosecution without following agency procedures. The draft enforcement language is more specific and is less open to arbitrary interpretation. An improvement in this area is the elimination of automatic enforcement for non-drinking water proficiency testing failures (see section on proficiency testing, below for details).

Initial and Continuing Calibration Verification [NR 149.44(6) and (7)]

Initial Calibration Verification, (ICV), is performed whenever a calibration is established, using a standard from a source different than calibration standards. It isn't retesting the standards, but an independent means to verify the calibration's validity. Tests performed by instruments that follow the Nernst equation or other scientific law (DO, ISE, pH) are exempt from initial calibration verification. For those tests without a calibration step, such as solids, there obviously is no ICV. Laboratories can substitute quality control samples (QCS, or "blinds") analyzed three times per year for ICVs.

Continuing Calibration Verification (CCV) is performed on days when a full calibration is not carried out, using a standard from the same source as the initial calibration. This is referred to as the *Opening CCV*. You have been analyzing a "known standard" for some tests for years— this is the opening CCV. A *Closing CCV,* which ensures that your instrument has not drifted during analysis, is analyzed at the conclusion of the batch and could likely be the same sample used for the opening CCV. The default

acceptance criteria for CCVs (±10% of the true value for inorganics and metals, ±15% for organics) has not changed from the current NR149.

Do I have to analyze *Closing CCVs*? Only if the method your laboratory follows requires closing CCVs. If not (which is the case for Ammonia, BOD, Nonfilterable Residue and Total Phosphorus reference methods), then a laboratory has the option to use the *Opening CCV* from the next batch of samples, provided that instrument conditions have not changed. The biggest risk is that one may have to qualify data from the previous analysis day if the opening CCV is not acceptable.

Refer to the tables on the last two pages for the specific ICV and CCV requirements for Ammonia, BOD, Nonfilterable Residue and Total Phosphorus.

Laboratory Support Equipment Calibration [NR 149.44 (3)]

Any equipment used in generating results that is not an instrument is considered to be "support equipment". This includes: analytical and top-loading balances, autoclaves, freezers, incubators, mechanical and automatic pipettors, burets, diluters and dispensers (that are not Class A glassware), ovens, refrigerators, thermometers, IR guns and other temperature-monitoring devices, and water baths. The current NR149 does not provide specific requirements other than "Calibration and maintenance of all test instruments and equipment as necessary to maintain accuracy" in sec. 149.14 (3)(a). The specificity in this section eliminates the interpretation of "as necessary" and clearly specifies frequencies for calibration, verification, acceptability criteria and options when equipment does not meet these specifications.

The following table summarizes these requirements.

Support Equipment & Usage	Calibration Frequency and How
Thermometers, IR guns, thermocouples, data-loggers, etc.	At least yearly, against a thermometer traceable to NIST
Autoclaves, incubators, ovens and water baths when in use as part of a method	Each day of use, temperature monitored to method or rule-specified criteria [1]
Refrigerators, freezers, ovens and incubators holding samples continuously	Each day of use, temperature monitored to method or rule-specified criteria [1]
Analytical balances	At least monthly, with two weights- one in the gram range and one in milligram range weight traceable to or verified against those traceable to NIST
Non-analytical balances	At least monthly, with one weight in range of expected use with weight traceable to or verified against those traceable to NIST
Mechanical and automatic pipettors, burets, dilutors and dispensers used in analytical procedures	At least quarterly, accuracy checked (mass: volume agreement)
Weights used to verify accuracy of balances	Traceable to NIST and suitable class; certified for accuracy every three years by external metrology service

[1] You do not have to monitor temperatures on days when analyses are not conducted (including weekends and holidays), provided that thermostats are set to maintain proper operating temperature.

Length of the Current Draft

Three years ago, when the NR 149 Rule Advisory Committee (RAC) was convened, the group agreed that the current NR149 contained many requirements that were open to interpretation. The RAC sought to find a balance between specificity of regulation without compromising the flexibility for compliance sought by laboratories. In doing this, we were faced with developing rule language to address virtually every scenario in current methods and practices, for every laboratory that participates in the program. If your laboratory only performs the routine WPDES-required tests, many of the details simply do not apply to your operation. The challenge is to distill what applies and what can be disregarded. The way the draft is formatted does not allow a direct comparison to the current NR 149. If one converts the current NR149 to the format of the draft, the current NR 149 becomes nearly 40 pages in length.

By changing the way that laboratories will be certified, we ended up having to produce the tables which comprise Appendices I and II. These 29 tables virtually double the length of the draft rule- and replace less than 2 pages of the current code, by comparison. The level of specificity, especially in Subchapter VII- Quality Systems, will provide specific detail, compared to broad statements such as "Calibration and maintenance of all test instruments and equipment as necessary to maintain accuracy" in the current NR 149.14 (3)(a).

Why can't this be written in English? Unfortunately, when creating Administrative Code, we had to follow a very specific style, using language that is as foreign to chemists as chemistry lingo is foreign to lawmakers. These is little we can do to change how code is written, but we can and will provide the tools necessary for laboratories to determine just what the language means to their particular operation.

Proficiency Testing [Subchapter V, NR 149.22-28]

Whether you call them PTs or reference samples, there are very few changes proposed in the draft. The revision proposes expanding the timeframe for analysis to anytime during the current certification or registration period, as long as the reports are received by the DNR by August 15th for renewal. For applications, the timeframe remains within 6 months of application. PTs will be required on a per-analyte basis, yet most laboratories will not be required to purchase additional PTs as the analytes are already in the mixes purchased for maintaining your current certifications. There are analytical techniques, such as metals by Flame AA, specifically exempted from proficiency testing requirements— you will no longer struggle with finding PTs with appropriate concentrations.

A list of required PTs will be published annually, after concurrence of the Laboratory Certification Council. For annual renewal there are very few changes, and the additional time for analysis will reduce some of the additional cost associated with "rapid-response" type PTs that laboratories face as renewal draws near.

How does this apply to BOD, Ammonia, Nonfilterable Residue (TSS) and Total Phosphorus?

Test	PT Requirements for Annual Renewal
BOD and CBOD	One acceptable PT, analyzed after 9/1 and reported to DNR by 8/15
Ammonia	One acceptable PT, analyzed after 9/1 and reported to DNR by 8/15
Nonfilterable Residue	One acceptable PT, analyzed after 9/1 and reported to DNR by 8/15
Total Phosphorus	One acceptable PT, analyzed after 9/1 and reported to DNR by 8/15

PTs & Enforcement We are doing away with automatically issuing enforcement for successive PT failures- instead, a laboratory will not be renewed if it does not submit an acceptable PT for renewal. After the first failure, the laboratory must obviously analyze a second PT. If that one is acceptable, the analytical technique/analyte combination will be renewed. If not, then hopefully the third PT will be the

charm. However, if a laboratory fails 3 PTs in a year, they will be required to submit 2 acceptable PTs for renewal. The actions taken by laboratories to address PT failures are not changing- we've just eliminated the hassle of the NONs and NOVs. Drinking water proficiency testing failure and enforcement, however, remains the same as EPA sets forth very specific requirements that we must follow.

Purpose and Value of Second Source Materials

The use of second source standards to verify calibration has been incorporated into many newer methods written by EPA and most other organizations. Recent training by the program and WI State Laboratory of Hygiene promotes using a different source for "known standards". A second source provides an independent verification that the laboratory is generating accurate results. Use of a second source can also assist when there are dilution errors when preparing calibration standards. The proposed rule places less emphasis on matrix-specific quality control (matrix spikes, matrix spike duplicates and sample replicates) to determine overall performance. Instead, batch acceptability is determined by the Laboratory Control Sample, (LCS) which is made using a second source standard spiked into reagent water. Many laboratories have already adopted the practice of using a second source for their "known standards", especially for total phosphorus analysis.

The Relationship Between Laboratory Control Samples, Matrix Spikes/Matrix Spike Duplicates, and Quality Control Samples [NR 149.48 (4), (5) and (8)]

A *Laboratory Control Sample* (*LCS*) is a sample of reagent water, spiked with a second source standard. Because LCSs are devoid of matrix interference, they are a better indication of a laboratory's ability to generate accurate data than matrix spikes. For tests that require a digestion or distillation, one Laboratory Control Sample (LCS) is processed with each set of samples prepared together. When samples are analyzed directly, one LCS is required daily. If the laboratory analyzes 7 or fewer samples for any quality system matrix in a week (wastewater influent and effluent are considered to be separate quality control matrices), a single LCS is all that is required each week. For BOD and CBOD, the LCS is GGA, as specified by the method. Results of LCS are to be evaluated against acceptance criteria which will be established by the DNR, specified in an approved method, or from in-house limits.

Matrix Spikes and *Matrix Spike Duplicates* (*MS/MSDs*) are **only** required if specified in an analytical method, project plan or by client agreement. They are not required if your laboratory follows *Standard Methods* methods, period. Many older EPA methods do not require their analyses either. Matrix spikes, when spiked with a second source standard, can be substituted for the LCS, provided that the laboratory evaluates their acceptance using the control limits for LCS.

Quality Control Samples (*QCS*) are the "blind standards" that laboratories have been analyzing for years. It is the intent of the program that the QCS will only be required if a laboratory does not use a second source standard for ICV and LCS.

It is important to point out the potential cost-savings in reagent purchase to laboratories that opt to use second source standards for ICVs and LCSs rather than continuing to participate in QCS studies. Based on catalog prices from common reagent vendors (Hach, Fisher, NCL, VWR), calibration standards for ammonia range from $10-$30 for 500-mLs. It is possible, that a single bottle of each source (2 bottles total) would provide a sufficient volume of standard for a year's worth of calibrations in smaller laboratories, so ammonia standard costs could be as low as $20-$60. To compare, the cost of purchasing QCS (APG, ERA, NSI, RTC, Wibby and WSLH) range from $120-$170/year. Even if a laboratory purchased 2 sets of standards (a total of 4 bottles) in a year, the most they would spend would only approach the cost of the QCS. Similarly, phosphorus standards range from $8-$30 for 500-mLs for an annual cost of $16-$60 (for a single bottle of each source) with annual QCS costs ranging from $120-

$150/year. Remember, since matrix spikes and replicates are no longer required, there will be one fewer sample to be analyzed with each 20 samples (which may offset any additional time or reagent usage).

Sample Handling and the 15-Minute Rule [NR 149.46 (3)]

Sample handling and preservation requirements are established by EPA, in 40 CFR Parts 136 and 141 for wastewater and drinking water respectively. Administrative codes, which must be as stringent as the federal regulations, require sample preservation immediately upon collection, with a few exceptions (i.e., metals in drinking water). The 15-minute rule begins at the moment samples are removed from an autosampler after a composite collection cycle has been completed, or at the time a grab sample is taken.

NR 219, Table F, footnote 2 states "All samples requiring preservation at ≤6ºC must be cooled immediately after collection, but not frozen." When we try to determine what immediately means, we rely on the explanation used to define "analyze immediately", since it is not logical to have a different definitions of "immediately" for sample preservation and sample analysis. Footnote 4 of Table F in NR 219 has strong suggestions about analyzing samples as soon as possible after collection. The note, referring to immediate analysis states: "The term 'analyze immediately' usually means within 15 minutes or less of sample collection." Footnote 2 can then be translated into "All samples requiring preservation at ≤6ºC must be cooled within 15 minutes or less of sample collection, but not frozen." A similar argument can be made for chemical preservation. We could strictly require preservation "IMMEDIATELY", or allow a 15-minute window and still maintain that a sample was preserved immediately.

How does this apply to BOD, Ammonia, Nonfilterable Residue (TSS) and Total Phosphorus?

Test	If Not at Laboratory in 15 Minutes
Ammonia	Sample transported ≤ 6º C (on ice) and preserved with H_2SO_4
BOD and CBOD	Sample transported ≤ 6º C (on ice)
Nonfilterable Residue	Sample transported ≤ 6º C (on ice)
Total Phosphorus	Sample transported ≤ 6º C (on ice) and preserved with H_2SO_4

Sample Identification and Labeling [NR 149.46 (3)]

Samples are required to be assigned a unique identification code, which is used to associate the sample with all relevant data and results. The sample container is to be labeled so that samples are not confused. If your laboratory performs all required analyses daily, then all that is required is that you demonstrate that the influent will not be confused for the effluent (I and E labeled containers will suffice). If you store samples to analyze several days together in a larger batch, then sample identifiers could be as simple as 5/1/06—E and 5/3/06—E. This same code would then used on benchsheets to identify each sample. This identification code could be written directly on the sample container with a grease pencil, permanent marker or placed on a label, which can be easily removed.

Guidance, Forms & Templates and Training

At the onset of this rule revision, the program made a firm commitment to the RAC that it would develop guidance documents and many associated tools needed by laboratories to comply with these changes. A "digest version" of the code, which distills the requirements for smaller laboratories- especially those associated with wastewater treatment plants, is in process. Forms for reagent tracking, sample receipt, and benchsheets for ammonia, BOD, nonfilterable residue and total phosphorus are near completion. A revised quality manual template is also in the works. Training? Of course- all in due time.

The completion of the revision process is likely to take months— and implementation cannot begin until *after* the rule is finalized by the legislature. For more details on how the draft NR149 will impact your laboratory, please contact Diane Drinkman at (608)264-8950 or Diane.Drinkman@dnr.state.wi.us or Alfredo Sotomayor at (608)266-9257 or Alfredo.Sotomayor@ dnr.state.wi.us.

Calibration and Quality Control Elements and Specific Requirements for Ammonia, BOD, Nonfilterable Residue and Total Phosphorus

Ammonia by Ion Selective Electrode			
CALIBRATION OR QC ELEMENT	ACRONYM	SPECIFIC REQUIREMENTS	ACCEPTANCE CRITERIA
Calibration- ISE Meter		Daily, 2 standards minimum	Slope = -57 ± 3 unless different in manual
Initial Calibration Verification	ICV	Exempt	
Continuing Calibration Verification	CCV	No opening CCV- meter calibrated daily 1 at end using same source as calibration standards and after 20 if >20 samples analyzed	90-110%
Laboratory Control Sample	LCS	1/analytical batch using second source (1/week if ≤ 7 influents and ≤7 effluents analyzed as single batch)	Control limits to be published by DNR, from method or generated in-house
Method Blank		1/analytical batch; needed daily to assess potential contamination	<LOD [1]
Matrix Spike	MS/MSD	Can substitute MS for LCS; must be spiked using second source Not required by method	If substituted for LCS, must use LCS acceptance criteria Control limits to be published by DNR, from method or generated in-house
Sample Replicate		Not required by method	Control limits to be published by DNR, from method or generated in-house
Quality Control Sample	QCS	Only required if not using second source for spiking LCS or MS (if substituted for LCS)	If analyzed, acceptance determined by provider
BOD			
CALIBRATION OR QC ELEMENT	ACRONYM	SPECIFIC REQUIREMENTS	ACCEPTANCE CRITERIA
Calibration- DO Meter		Daily	Air-saturated water, water-saturated air or Winkler technique
Initial Calibration Verification	ICV	Exempt	
Continuing Calibration Verification	CCV	Impossible to verify calibration without recalibrating	
Laboratory Control Sample	LCS	Use GGA; 1/week if ≤ 7 influents and ≤7 effluents analyzed weekly	167.5-228.5 mg/L as specified in method 5210B
Method Blank		1 daily and per batch of dilution water (if use more than 1 batch dilution water); needed to assess dilution water per method	<0.2 mg/L, as specified in method 5210B
Matrix Spike	MS/MSD	Cannot spike BOD- not required	
Sample Replicate		Not required by method	
Quality Control Sample	QCS	Not required [2]	If analyzed, acceptance determined by provider

Nonfilterable Residue (TSS)			
CALIBRATION OR QC ELEMENT	ACRONYM	SPECIFIC REQUIREMENTS	ACCEPTANCE CRITERIA
Calibration		N/A; analytical balance verified at least monthly	
Initial Calibration Verification	ICV	N/A	
Continuing Calibration Verification	CCV	Exempt	
Laboratory Control Sample	LCS	Exempt	
Method Blank		Not required by method	
Matrix Spike	MS/MSD	Not required by method	
Sample Replicate		Not required by method	
Quality Control Sample	QCS	Exempt [1]	If analyzed, acceptance determined by provider

Total Phosphorus			
CALIBRATION OR QC ELEMENT	ACRONYM	SPECIFIC REQUIREMENTS	ACCEPTANCE CRITERIA
Calibration		Minimum annually [3], 3 standards minimum, linear curve	R≥ 0.995
Initial Calibration Verification	ICV	Second source standard OR analysis of QCS	90-110%
Continuing Calibration Verification	CCV	1 at beginning and end using same source as calibration standards and after 20 if >20 samples analyzed	90-110%
Laboratory Control Sample	LCS	1/preparation batch using second source (1/week if ≤ 7 influents and ≤7 effluents analyzed as single batch)	Control limits to be published by DNR, from method or generated in-house
Method Blank		1/preparation batch; needed to assess daily contamination and possibly for meter zeroing	<LOD [2]
Matrix Spike	MS/MSD	Can substitute MS for LCS; must be spiked using second source Not required by method; must to be spiked using second source	If substituted for LCS, must use LCS acceptance criteria Control limits to be published by DNR, from method or generated in-house
Sample Replicate		Not required by method	Control limits to be published by DNR, from method or generated in-house
Quality Control Sample	QCS	Only required if not using second source for spiking LCS or MS (if substituted for LCS)	If analyzed, acceptance determined by provider

[1] A sample in analytical batch is to be reanalyzed or qualified if the method blank exceeds the highest of any of the limit of detection, 5% of the permit limit or 10% of measured concentration in the sample.
[2] The exemptions listed in sec. 149.48(8)(a) will be clarified so that QCS is exempt when analyte is not amenable to spiking, in addition to when an instrument is calibrated to a universally accepted scientific law or scale (such as DO and ISE meters).
[3] A new calibration curve is required if laboratory changes lot number of any reagent used for test.